ustomer No. 35744

### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

e Application of: Pilon, Aprile, et al.

Serial No.:

10/647,371

Art Unit:

1646

Official Filing Date: August 25, 2003

For:

METHODS AND COMPOSITIONS FOR THE TREATMENT OF FIBROTIC CONDITIONS AND IMPAIRED LUNG FUNCTION AND

TO ENHANCE LYMPHOCYTE PRODUCTION

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

#### **CERTIFICATE OF MAILING**

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to Commissioner for Patents, Alexandria, VA 22313-1450

#### INFORMATION DISCLOSURE STATEMENT

Applicant respectfully submits this Information Disclosure Statement pursuant to 37 C.F.R. §§ 1.97 and 1.98 in order to comply with the duty of disclosure under 37 C.F.R. § 1.56.

I. List of Patents, Publications, or Other Information

References are listed on the attached modified PTO Form No. 1449. It is respectfully requested that the information be expressly considered during the prosecution of this application and that the references be made of record therein and appear among the "References" Cited" on any patent to issue therefrom.

#### II. Copies

A copy of the listed references is enclosed for the convenience of the Examiner.

Any patents, publications or other information which are listed on the attached modified PTO

Form No. 1449 but which are not enclosed herewith were previously cited by or submitted to the

PTO in one of the following applications which has been relied upon for an earlier filing date

under 35 U.S.C. 120:

U.S. Serial Number	U.S. Filing Date
09/549,926	04/14/2000
09/120,264	07/21/1998
09/087,210	05/28/1998
08/864,357	05/28/1997

Should the examiner desire, a copy of any of these previously cited unenclosed references can be made available for his convenience.

### III. Concise Explanation of the Relevance

A concise explanation of the relevance of all patents, publications or other information listed that is not in the English language is as follows: WO96/09831, in German, discloses the use of lung surfactant for the treatment of diseases like adult ARDS.

# IV. Cross Reference to Related Applications

The Examiner is advised that the following applications belonging to the applicant contain subject matter that may be related to the present application. By bringing these applications to the Examiner's attention, Applicants do not waive the confidentiality provisions of 35 U.S.C. §122.

Serial No.	Filing Date
08/864,357	05/28/1997

09/087,210	05/28/1998
09/120,264	07/21/1998
09/549,926	04/14/2000
09/835,784	04/13/2001
09/861,688	05/21/2001
09/898,616	07/02/2001
10/045,534	10/24/2001
10/187,498	07/02/2002
10/638,448	08/11/2003
PCT/US98/11026	05/28/1998
PCT/US99/16312	07/19/1999
PCT/US01/12126	04/13/2001
PCT/US02/20836	07/02/2002

## **FEES**

This IDS is being filed under 37 C.F.R. §1.97(b)(3) before the mailing of the first action on the merits. No fee or certification is required. However, the Director is hereby authorized to charge any fees associated with this information disclosure statement to Deposit Account No. 50-0540.

Respectfully submitted,

Dated: April 19, 2004

Barry Evans

Reg. No. 22,802

KRAMER LEVIN NAFTALIS & FRANKEL LLP

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Sheet 5

Substitute for form 1449A/PTO

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Complete if Known			
Application Number	08/864,357		
Filing Date	May 28, 1997		
First Named Inventor	Pilon et al.		
Group Art Unit	1646		
Examiner Name	Romeo, D.		
Attorney Docket Number	116142-00085		

			U.S. PATENT DOCUM	MENTS	
Examiner Cite No.1 Number Kind Code2		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Releva Passages or Relevant Figures Appear	
	AA	(if known) 5,696,092	Patierno et al.	12/9/97	
	AB	5,266,562	Mukherjee et al.	11/30/93	
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	FOREIGN PATENT DOCUMENTS							
Examiner Initials*	Cite No. <sup>1</sup>	Office <sup>3</sup>		ent Code <sup>5</sup> (if nown)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sub>6</sub>
	ВА		WO96/09831		Germann, Paul- George	04/04/96		
	ВВ		WO96 40657		The George Washington University	12/19/96		
	BC		WO 88 08983		Cederholm	11/17/88		

Examiner Signature	Date Considered	

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<sup>1</sup> Unique citation designation number. 2 See attached Kinds of U.S. Patent Documents, 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark hee if English language Translation is attached.

PTO/SB/08A (10-96)

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# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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of 5

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Examiner Name	Romeo, D			
Attorney Docket Number	116142-00085			

	OTHER PRIOR ART NON PATENT LITERATURE DOCUMENTS					
Examiner Initials *	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T 2			
	CA	ABMAN et al., "Pathophysiology and Treatment of Bronchopulmonary Dysplasia: Current Issues." Pediatric Clinics of North America, Vol. 41 No. 2, pp. 277-315 (1994).				
	СВ	AKIYAMA et al., "Fibronectin and Integrins in Invasion" Cancer and Metastasis Reviews. Vol. 14, pp. 173-189 (1995).				
	СС	ANDERSSON et al., "Heterologous Expression of Human Uteroglobin/Polychlorinated Biphenyl-binding Protein." J. Biol. Chem., Vol. 269 pp.19081-19087 (1994).				
	CD	AOKI et al., "Isolation of Human Uteroglobin from Blood Filtrate." Mol. Hum. Reprod., Vol. 2, pp. 489-497 (1996).				
	CE	ASSMANN et al., "Familial Glomerulonephritis Characterized by Massive" Am. J. Kid. Dis., Vol 25, pp. 781-791 (1995).				
	CF BARNES et al., "Structural Basis for Calcium" JMB, Vol. 256, pp. 392-404 (1996).					
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	СН	BEIER, H.M., "Uteroglobin: A Hormone-dependent Endometrial Protein Involved in blastocyst Development," Biochem. Biophys. Acta, Vol. 160, pp. 289-291 (1968).				
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	Cì	BERNARD, et al., "Serum Clara Cell Protein: An Indicator," Env. Res., Vol. 66, pp. 96-104 (1994).				
	СК	BERNARD et al., "Clara Cell Protein in Serum and Bronchoalveolar Lavage," Eur. Respir. J. Vol. 5, pp. 1231-1238 (1992a).				

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Examiner	Date	
Signature	Considered	

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<sup>&</sup>lt;sup>1</sup> Unique citation designation number. <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Complete if Known Application Number 08/864,357 May 28, 1997 Filing Date First Named Inventor Pilon, et al. Group Art Unit 1646 **Examiner Name** Romeo, D 116142-00085 Attorney Docket Number

(use as many sheets as necessary)

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of T² Cite Examiner the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue No.1 Initials \* number(s), publisher, city and/or country where published. BERNARD et al., "Human Urinary Protein 1: Evidence for Identity with the Clara Cell Protein and Occurrence in CL Respiratory Tract and Urogenital Secretions," Clin. Chim. Act., Vol. 207, pp. 239-249 (1992b). BERNARD et al., "Selective Increase in the Urinary Execretion of Protein 1 (Clara Cell protein) and other low СМ molecular weight proteins during normal pregnancy," Scand. J. Clin. Lab. Invest. Vol. 52, pp. 871-878 (1992c). BERNARD et al., "Protein 1 is a Secretroy Protein for the Respiratory and Urogenital Tracts Identical to the Clara CN Cell Protein," Clin. Chem. Vol. 39, pp. 434-435 (1992d). BERNARD et al., "Determination by Latex Immunoassay of Protein 1 in Normal and Pathological Urine," Clin. CO Chem. Acta., Vol 201, pp. 231-246 (1991). BERNARD et al., "Urine Protein 1: a Sex-Dependent Marker of Tubular or Glomerular Dysfunction," Clin. Chem. CP Vol. 35, pp. 2141-2142 (1989). CQ BITTERMAN et al., "Role of Fibronectin as a ...," J. Cell. Biol. Vol. 97 pp. 1925-1932 (1983). CAMUSSI et al., "Anti-inflammatory peptides (antiflammins) inhibit synthesis of platelet-activating factor, neutrophil CR aggregation, and chemotaxis, and intradermal inflammatory reactions, " J. Exp. Med., Vol. 171, pp. 913-927 CAMUSSI et al., "Antiflammins Inhibit Synthesis of Platelet-Activating....," Biochem, Mol. Biol. and Physiol. of CS Phospholipase A2 and its Regulatory Factors, pp. 161-172 (1990). CHAN et al., "Antiflammins: Inhibit of Endotoxin-induced Uveitis in Lewis Rats," In Ocular Immunology Today CT (Usui, Ohno, and Aoki. Eds.). Elsevior Science Publishers, Amsterdam, pp. 467-470 (1990). CHAN et al., "Effects of Antiflammins on Endotoxin-Induced Uveitis in Rats, " Arch. Opthamol., Vol. 109, pp. 278-CU 281 (1991). CHIESA M et al. "Significant Increase in Immunoregulatory Protein Blastokinin/Uteroglobin in IgA/Fibronectin CV Complexes in Sera of Patients with IgA Nephropathy" Nephrology Dialysis Transplantation, Vol. 15, Mo. 9 p. A39 (2000).DENNIS et al., "Multiple forms of phospholipase A2 in macrophages capable of arachidonic acid release for

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1	Examiner	Date		
	Signature	Considered		

cicosanoid biosynthesis," Adv. Prostaglandin Thromboxane Leukot Res., Vol. 23, pp. 75-80 (1995a).

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Substitute for form 1449A/PTO		Complete if Known
INCORMATION DIGGLOCUES	Application Number	08/864,357
INFORMATION DISCLOSURE	Filing Date	May 28, 1997
STATEMENT BY APPLICANT	First Named Inventor	Pilon, et al.
	Group Art Unit	1646
(use as many sheets as necessary)	Examiner Name	Romeo, D
Sheet 4 of 4	Attorney Docket Number	116142-00085

		OTHER PRIOR ART NON PATENT LITERATURE DOCUMENTS	
Examiner Initials *	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
	сх	DENNIS E.A., "Potential phopholipase A2s involved in inflammatory diseases," Agents Actions Suppl., Vol. 46, pp 35-39 (1995b).	
	CY	DHANIREDDY et al., "Ontogeny of Uteroglobin in Relation to, " Pd. Res., 299A."	
	cz	DIERYNCK et al., "The human Clara cell protein: biochemical and biological," Mult. Schler., Vol. 1, No. 6, pp. 385-387 (1996).	
	DA	EDELSON et al., "Acute Lung Injury Induced by Phospholipase A <sub>2</sub> : Structural and Functional Changes," Am Rev. Respir. Dis., Vol. 143, pp 1102-1109 (1991).	
	DB	GUY et al., "Surfactant-producing Rabbit Pulmonary Alvcolar Type II Cells," BBRC, Vol. 189, pp. 662-669 (1992).	
74.	DC	KIKUKAWA, et al., "Partial Characterization of a Uteroglobin-Like Protein in the Human Uterus and Its Temporal Relationship to Prostaglandin Levels in This Organ," J. Clin. Endo & Met. 67(2): 315-321.	
	DD	LEYTON et al. "Recombinant Human Uteroglobin Inhibits the In Vitro Invasiveness, " Cancer Res., Vol. 54 pp 3696-3699 (1994).	
	DE	MATTHEWS et al., "Crystallization and Characterization of the Recombinant Human Clara Cell 10-kDa Protein", PROTEINS: Structure, Function and Genetics, 20: 191-196 (1994).	
	DF	MUKHERJEE et al., "Modulation of Cellular Response to Antigens by Uteroglobin and Transglutaminase" Adv. Exp. Med. Biol., 231:135-152 (1988).	
	DG	MUKERJEE eta I., "Regulation of Extracellular Phospholipase A2 Activity: Implication for Inflammatory Diseases" DNA and Cell Biology, Vol. 11, No. 3 pp. 233-243 (1992-04).	
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	DK	RENNARD et al., "Production of Fibronectin by the Human Alveolar Macrophase: Mechanism for the Recruitment of Fibroblasts to Sites of Tissue Injury in Interstitial Lung Diseases" Proc. Natl. Acad. Sci. USA, 78(11): 7147-7151 (1988).	
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INITO!	DALATION	DIO	01.001105	Application Number	08/864,357	
			CLOSURE	Filing Date	May 28, 1997	
STATEMENT BY APPLICANT			PPLICANT	First Named Inventor	Pilon, et al.	
				Group Art Unit	1646	
(use as many sheets as necessary)				Examiner Name	Romeo, D	
Sheet	5	of	5	Attorney Docket Number	116142-00085	

DM	VAN VYVE et al., "Protein content in bronchoalveolar lavage fluid of patients with asthma and control subjects", J. of Allergy and Clin. Immun., vol. 95 no. 1 pp. 60-68 (1995)	
DN	WATTS et al., "Effect of Dexamethasone Therapy on Fibronectin and Albumin Levels in Lung Secretions of Infants with Bronchopulmonary Dysplasia" J. Pediat. 121:597-607 (1992).	
DO	ZHANG ZH et al., "Severe Fibronectin-Deposit Renal Glomerular Disease in Mice Lacking Uteroglobin." Science, Vol. 276, No. 5317 pp 1408-1412 (1997).	
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